



PERFORMANCE QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



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1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Bacteriological Incubator.
- To determine that the Bacteriological Incubator performs as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets predefined specifications under normal conditions and where appropriate for worst case situations.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Bacteriological Incubator
ID Number
Location	Incubation Room

3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure.
Refer Performance Verification Checklist as per Annexure - I.

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II.



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5.0 Recommendations and Conclusions:

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6.0 References:

- Design Qualification
- Installation Qualification
- Operational Qualification
- Standard Operating Procedure

7.0 Annexure

- Annexure - I : Performance Verification Checklist
- Annexure - II : List of Changes / Deviation.
- Annexure - III : Performance Qualification Report.

8.0 Abbreviations:

SOP : Standard Operating Procedure

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
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Approved By				



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Annexure - I

Checklist for Performance Verification

Temperature Mapping of Bacteriological Incubator				
Set Temperature	Acceptance Criteria	Temperature Mapping Result	Remarks	Verification Done By

Note : -

Remarks: - Performance Verification of Bacteriological Incubator - Complies / Does not comply.



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Annexure - II

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By: